



St. Louis  
Orthopedic  
Institute, Inc.

7731 '99 DEC 10 10:02

November 30, 1999

Thomas E. Albus, M.D.  
Arthritis Surgery

Ryan W. Couchman, M.D.  
Sports Medicine  
Arthritis Surgery

D. Wade Hammond, M.D.  
Arthritis Surgery  
Sports Medicine

David R. Lange, M.D.  
Spine Surgery

Richard E. Lord, M.D.  
General Orthopedics

George A. Luther, M.D.  
Foot Surgery  
Arthritis Surgery

Michael P. Nogalski, M.D.  
Sports Medicine  
Knee and Shoulder Surgery

Donald L. Pruitt, M.D.  
Hand Surgery  
General Orthopedics

Bernard C. Randolph, Jr., M.D.  
Physical Medicine  
Spine Care  
Electrodiagnostics

Robert A. Sciortino, M.D.  
Sports Medicine  
Arthritis Surgery

James C. Strickland, M.D.  
Arthritis Surgery  
Sports and Knee Surgery

David L. Stronsky, M.D.  
Adult Reconstruction of the Shoulder  
Adult Joint Replacement Surgery  
Foot Surgery

Robert E. Tucker, M.D.  
Hand Surgery  
Wrist and Elbow Surgery

Eileen P. Niesen, M.H.A., M.B.A.  
Administration

Business Office  
505 Couch, #25  
Kirkwood, MO 63122  
966-0111  
F 966-1023

Kirkwood  
505 Couch, 45  
Kirkwood, MO 63122  
966-0111  
F 966-2810

Creve Coeur  
621 S. New Ballas #499A  
St. Louis MO 63141  
966-0111  
F 569-6492

Bridgeton  
12277 DePaul, #200  
Bridgeton, MO 63044  
966-0111  
F 770-1649

Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852


Re: Docket # 97N-484S

Dear Sir:

I have written to the FDA previously about proposed regulation of bone allograft as devices. In order to prepare allograft for use in orthopedic applications, some "fashioning" of the bone is necessary prior to insertion. This "fashioning" of the appropriate size or shape is typically performed at the operating table by the surgeon or assistant or in other cases, by the vendor of the allograft (the Red Cross tissue banks or otherwise). Such manipulation of the bone does not require FDA oversight. Not only is such oversight not necessary from a scientific or safety point of view, but also likely would add to the significant expense and lack of availability of allograft bone. It is bad enough that donors of bone are in short supply, but to add unnecessary bureaucracy to the process likely would make the availability and cost such that a true harm would come to the public.

I encourage you to forget about the regulation of bone allograft. On a cynical note, it appears that this issue is a rather artificial one and unfortunately was started in an anti-competitive fashion by one or more manufactures of metal spinal implants (in direct competition with allograft).

Sincerely yours,

  
David R. Lange, M.D.  
DRL/p.o.-t: 12/02/99

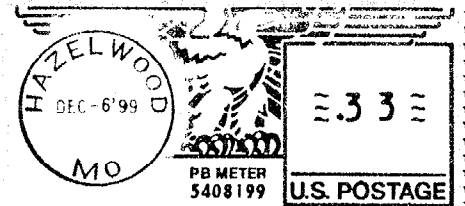
97N-484S

C77



St. Louis  
Orthopedic  
Institute, Inc.

Business Office  
505 Couch, #25  
St. Louis, MO 63122



Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852

20837-0001

